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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,038	02/09/2004	Todd F. Ovokaitys	2827.GEMA.CIP	6904

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EXAMINER	
SHAY, DAVID M	

ART UNIT	PAPER NUMBER
3735	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/775,038	OVOKAITYS ET AL.	
	Examiner	Art Unit	
	david shay	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *December 6, 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-145* is/are pending in the application.

4a) Of the above claim(s) *13-145* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :September 9, 2005 and October 16, 2006.

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Claims 13-145 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on January 3, 2008.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "subjecting the substance to a laser to modify the structure thereof"; ""providing a fractional frequency shift to said laser to traverse sparse constructive nodes through said bioactive substance"; altering said bioactive substance to modify nitric oxide production following ingestion of said bioactive substance"; modifying the structure of said bioactive substance to homogenize and flatten chemical bonds within said bioactive substance"; modifying the bioactive substance to enhance methylation after ingestion" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet,

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even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

It is noted that the terms: "subjecting the substance to a laser to modify the structure thereof"; ""providing a fractional frequency shift to said laser to traverse sparse constructive nodes through said bioactive substance"; altering said bioactive substance to modify nitric oxide production following ingestion of said bioactive substance"; modifying the structure of said bioactive substance to homogenize and flatten chemical bonds within said bioactive substance"; modifying the bioactive substance to enhance methylation after ingestion" satisfy the three pronged test for a means or step plus function recitation and with be treated as such herein. See MPEP 2181(I)

Applicant is required to cancel the new matter in the reply to this Office Action.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and

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Claims 1-12 are rejected under 35 U.S.C. 101 because the disclosed invention is inoperative and therefore lacks utility. Applicant has provided no evidence that the bioavailability of a substance can be altered by exposing the substance to laser radiation, and there is no prevailing physical or medical theory as to why the substance should behave in this manner on exposure to laser radiation, further none of the claimed compounds have been shown to be high Q molecules.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method as set forth, does not reasonably provide enablement for modifying the structure of a bioactive molecule in any environment simply by exposing it to any type of laser radiation with no particular parameters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The nature of the invention of producing nutrient products is not a field wherein extensive amounts of experimentation are required, however the amount of experimentation to determine various laser parameters required to effect the molecular changes in any environment is undue. This particularly in view of the fact that the guidance given appears to be in terms that are unfamiliar to one of ordinary skill in the art.

Claims 7-9 and 11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described

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which it is most nearly connected, to make and/or use the invention. Applicant has not sufficiently explained the term "sparse constructive nodes", including what they encompass, how they can be recognized, detected, or distinguished from other types of nodes (e.g. plentiful constructive nodes), and how the frequency shifts that "traverse" them are determined and produced. Similarly, in exactly what manner and by exactly what method the substances are modified in order to produce the various claimed results is not disclosed with sufficient specificity to enable one of ordinary skill in the art to perform the method.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The exact meaning of the terms "bioactive substance" and "bioavailability" as used in the claims is unclear. In claim 7 the exact meaning of the term "sparse constructive nodes" is unclear and how these nodes are "traversed" is unclear.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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(f) he did not himself invent the subject matter sought to be patented.

Claims 1-7 and 9 are rejected under 35 U.S.C. 102(f) as being clearly anticipated by Strachan (WO '187).

Strachan (WO '187) discloses the claimed invention.

Claims 1-7 and 9 are rejected under 35 U.S.C. 102(f) as being clearly anticipated by Strachan (US '564).

Strachan (US '564) discloses the claimed invention.

Claims 1-7 and 9 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Strachan (WO '187).

Strachan (WO '187) discloses the claimed invention.

Claims 1-7 and 9 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Strachan (US '564).

Strachan (US '564) discloses the claimed invention.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strachan (US '564) or (WO '187) in combination with Zeng et al. Strachan (US '564) and (WO '187) teach a method as claimed except for the discussion of the particular compounds to be used. Zeng et al teach that arginine is a simple amino acid. It would have been obvious to the artisan or ordinary

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skill to modify arginine by the method of Strachan (US '564) or (WO '187) since arginine is a simple amino acid, thus producing a method such as claimed.

Claims 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strachan (US '564) or (WO '187) in combination with Tada et al. Strachan (US '564) and (WO '187) teach a method as claimed except for the discussion of the particular compounds to be used. Tada et al teach that betaine (i.e.trimethylglycine) is a protein. It would have been obvious to the artisan or ordinary skill to modify betaine (i.e.trimethylglycine) by the method of Strachan (US '564) or (WO '187) since betaine (i.e.trimethylglycine) is a protien, thus producing a method such as claimed.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 6,811,564. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent anticipate the claims of the application. Accordingly, instant application

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elements A, B, C, and D while instant application claim 1 only requires elements A, B, and C. Thus it is apparent that the more specific patent claims encompass the instant application claims. Following the rationale in In re Goodman cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

Claims 1-12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-70 of U.S. Patent Application No. 10/774, 746. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application anticipate the claims of the instant application. Accordingly, instant application claims are not patentably distinct from the copending application claims. Here, the copending application claims require elements A, B, C, and D while instant application claims only requires elements A, B, and C. Thus it is apparent that the more specific copending application claims encompass the instant application claims. Following the rationale in In re Goodman cited in the preceding paragraph, where applicant has once been granted a patent containing a claim for the specific or narrower invention, applicant may not then obtain a second patent with a claim for the generic or broader invention without first submitting an appropriate terminal disclaimer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim 8 is rejected under the judicially created doctrine of obviousness-type double

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al. Zeng et al teach that arginine is a simple amino acid. It would have been obvious to the artisan or ordinary skill to modify arginine by the method of U.S. Patent No. 6,811,564, since arginine is a simple amino acid, thus producing a method such as claimed.

Claims 10-12 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 13 of U.S. Patent No. 6,811,564 in view of Tada et al. Tada et al teach that betaine (i.e.trimethylglycine) is a protein. It would have been obvious to the artisan or ordinary skill to modify betaine (i.e.trimethylglycine) by the method of U.S. Patent No. 6,811,564, since arginine is a protien, thus producing a method such as claimed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Tuesday through Friday from 6:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on Monday, Tuesday, Wednesday, Thursday, and Friday. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).